

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

FIKES et al.

Appl. No. 09/458,297

Filed: December 10, 1999

For: Inducing Cellular Immune

Responses To p53 Using Peptide and Nucleic Acid Compositions

Confirmation No. 8696

Art Unit: 1644

Examiner: Schwadron, R.B.

Atty. Docket:

2060.0120000/EKS/HCC/M-M

Second Supplemental Information Disclosure Statement

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. A copy of each document is also provided.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following, in regards to non-English language documents AM1, AP1, and AM2 cited on Form PTO 1449:

Document AM1, EP 0 226 513, is in the French language. It is believed that AM1 discloses HIV peptide derivatives. An English language abstract of document AM1 is attached as Document AS25;

Document AP1, WO 92/21033, is in the German language. It is believed that AP1 discloses peptides which bind MHC class I and class II molecules. An English language

abstract of document AP1 is located on page one of the document and another English language abstract is attached as Document AT25;

Document AM2, WO 94/11738, is in the German language. It is believed that AM2 discloses peptides which bind MHC class I and class II molecules. An English language abstract of document AM2 is located on page one of the document and another English language abstract is attached as Document AR26.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Second Supplemental Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

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Helene C. Carlson Agent for Applicants

Registration No. 47,473

Date: 8/15/03

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SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 2060.0120000	APPLICATION NO. 09/458,297
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	AM1	EP 0	226 513 A1	06/24/1987	Europe	-		X Ye
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	AP1	WO 9	2/21033 A1	11/26/1992	WIPO			. Y е Х N
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	AR	1	priming wit	, et al., "A h a free syn Press (1990)	ntiviral cytotoxic T cell thetic peptide," <i>J. Exp</i> .	l response i <i>Med. 171</i> :18	nduced by 15-1820,	in vivo Rockefeller
	AS	1	Repertoire	and Recognit	"Derivation of HLA-A11/K ^b ion of Human A11-Restrict ican Association of Immur	ed CTL Epit	opes." J.	nctional CTL Immunol.
	AT	1	Presentatio	n of Epitope:	"Differential Effects of s from Chimeric Peptides, crobiology (August 1994)	Flanking R	esidues on 68:5306-	n 5310,
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	AS	2	Bertoni, R. Chimpanzees (1998)	., et al., "H s," J. Immuno	Tuman Class I Supertypes and bl. 161:4447-4455, American	CTL Repe Associati	rtoires Ex on of Immu	tend to inologists
	AT	<u>2</u>	Bjorkman, P.J., et al., "Structure of the human class I histocompatibility antigen, HLA-A2," <i>Nature 329</i> :506-512, Macmillan Publishers, Ltd. (1987)					
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	AS	<u>3</u>	Site on Ia	Buus, S., et al., "Autologous Peptides Constitutively Occupy the Antigen Binding Site on Ia," <i>Science 242</i> :1045-1047, American Association for the Advancement of Science (1988)					
	AT	<u>3</u>	nonoverlar	Carreno, B.M., et al., "HLA-B37 and HLA-A2.1 molecules bind largely nonoverlapping sets of peptides," <i>Proc. Natl. Acad. Sci. USA</i> 87:3420-3424, National Academy Press (1990)					
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	AS	<u>4</u>	complex mo	De Bruijn, M.L.H., et al., "Peptide loading of empty major histocompatibility complex molecules on RMA-S cells allows the induction of primary cytotoxic T lymphocyte responses," Eur. J. Immunol. 21:2963-2970, VCH Verlagsgesellschaft mbH (1991)					toxic T
	AT	<u>4</u>	Del Val, M., et al., "Efficient Processing of an Antigenic Sequence for Presentation by MHC Class I Molecules Depends on Its Neighboring Residues in the Protein," Cell 66:1145-1153, Cell Press (1991)						
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	AT	12	residues o	ritical for pe	"Single amino acid change eptide-MHC binding and T Association of Immunolog	cell re	cogni	antigen d	define Immunol.
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	AR	13	Predictive	e Value of the	"Primary in Vivo Respons K ^b Binding Motif," <i>J. I</i> gists (February 1993)	ses to O mmunol.	valbum 150:1	nin. Prob 212-1222,	ing the The American
	AS	13	recognition	on by H-2-rest	, "Synthetic peptides as ricted cytolytic T cells ler University Press (19	specif	ns and	d competion HLA," J	tors in . Exp. Med.
	AT	13	Peptides :	Incorporating	, "Competitor Analogs fo a Putative Binding Motif , Cell Press (1990)	or Defin and Po	ed T C lyprol	Cell Antig	gens: olyglycine
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	AR	14	Morrison,	J., et al., "I	Identification of the nonamrole of pockets of HLA-A2 in Immunol. 22:903-907, VCH V	ner peptid	ognition b	y cytotoxic		
	AS	<u>14</u>	Niedermann, G., et al., "The proteolytic fragments generated by vertebrate proteosomes: Structural relationships to major histocompatibility complex class I binding peptides," Proc. Natl. Acad. Sci. USA 93:8572-8577, National Academy Press (1996)							
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	AT	<u>15</u>	Escherichi	.C., et al., "F ia coli," J. Bi rry and Molecul	iol. Ch	hem. 267:545	1-5459, A	Americ	LA-B27 can So	Isolated	i from ·
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	AS	<u>16</u>	Rammensee Molecules	Rammensee, HG., et al., "Peptides Naturally Presented by MHC Class I Molecules," Annu. Rev. Immunol. 11:213-244, Annual Reviews, Inc. (January 1993)					; I inuary 1993)
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	AS	<u>18</u>	Histocompa	Rötzschke, O., et al., "Characterization of Naturally Occurring Minor Histocompatibility Peptides Including H-4 and H-Y," <i>Science 249</i> :283-287, American Association for the Advancement of Science (1990)					
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	AT	<u>19</u>	hormone se	J., "Characte quence," in P timore, MD, p	ristics of the amino acids eptide Hormones, Parsons, o p.1-7 (1976)	as compond	ents of a Universit	peptide y Park		
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	AR	20	Ruppert, 3 Binding to	J., et al., "P o HLA-A2.1 Mol	rominent Role of Secondary ecules," <i>Cell 74</i> :929-937, C	Anchor Re Cell Press	sidues in (Septembe	Peptide r 1993)
	AS	<u>20</u>	recognition	Schulz, M., et al., "Major histocompatibility complex binding and T cell recognition of a viral nonapeptide containing a minimal tetrapeptide," Eur. J. Immunol. 21:1181-1185, VCH Verlagsgesellschaft mbH (1991)				ell " Eur. J.
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	AT	21	Profoundly	Shastri, N., et al., "Presentation of Endogenous Peptide/MHC Class I Complexes Is Profoundly Influenced by Specific C-Terminal Flanking Residues," <i>J. Immunol.</i> 155: 4339-4346, The American Association of Immunologists (1995)				
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SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 2060.0120000	APPLICATION NO. 09/458,297
APPLICANT Fikes et al.	

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

FIKES et al.

Appl. No. 09/458,297

Filed: December 10, 1999

For:

Inducing Cellular Immune

Responses To p53 Using Peptide and Nucleic Acid Compositions

Confirmation No. 8696

Art Unit: 1644

Examiner: Schwadron, R.B.

Atty. Docket:

2060.0120000/EKS/HCC/M-M

Third Supplemental Information Disclosure Statement

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Third Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Second Supplemental Information Disclosure Statement filed herewith in connection with the above-captioned application. A copy of each document is also provided.

The Examiner's attention is directed to the following co-pending U.S. patent applications:

U.S. Application No. 08/205,713, filed March 4, 1994;

U.S. Application No. 08/344,824, filed November 23, 1994;

U.S. Application No. 08/347,610, filed December 1, 1994;

U.S. Application No. 08/591,502, filed May 20, 1996;

- U.S. Application No. 09/017,524, filed February 3, 1998;
- U.S. Application No. 09/665,510, filed September 19, 2000;
- U.S. Application No. 10/149,140, § 371 date November 18, 2002;

which are directed to related technical subject matter. The identification of these U.S. patent applications is not to be construed as a waiver of secrecy as to these applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Third Supplemental Information Disclosure Statement is being filed before the

FIKES *et al*. Appl. No. 09/458,297

- 3 -

mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Gelenellarlon

Helene C. Carlson Agent for Applicants

Registration No. 47,473

Date: 8/15/03

1100 New York Avenue, N.W. Washington, D.C. 20005-3934 (202) 371-2600

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ATTY. DOCKET NO. 2060.0120000	APPLICATION NO. 09/458,297
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INFORMATION DISCLOSURE STATEMENT

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December 10, 1999 1644 U.S. PATENT DOCUMENTS EXAMINER INITIAL DOCUMENT NUMBER DATE NAME CLASS SUB-CLASS FILING DATE AΑ AΒ AC ΑD ΑE AF AG AΗ ΔТ АJ ΑK FOREIGN PATENT DOCUMENTS EXAMINER DOCUMENT NUMBER INITIAL DATE COUNTRY CLASS SUB-CLASS TRANSLATION ALNo Yes AM No Yes AN No Yes ΑO No Yes ΑP No OTHER (Including Author, Title, Date, Pertinent Pages, etc.) Harris, N., et al., "Molecular Basis for Heterogeneity of the Human p53 Protein, " Mol. Cell. Biol. 6:4650-4656, American Society for Microbiology AR <u>27</u> (1986). Kawashima, I., et al., "The Multi-epitope Approach for Immunotherapy for Cancer: Identification of Several CTL Epitopes from Various Tumor-Associated AS 27 Antigens Expressed on Solid Epithelial Tumors," Hum. Immunol. 59:1-14, American Society for Histocompatibility and Immunogenetics (1998). Knuth, A., et al., "Cellular and humoral immune responses against cancer: AT 27 implications for cancer vaccines, " Curr. Opin. Immunol. 3:659-664, Current Biology Ltd. (1991). EXAMINER DATE CONSIDERED



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	AS	<u>28</u>	"Neoplasia," in Robbins Pathologic Basis of Disease, 4th edition, Cotran, R.S., et al., eds., W.B. Saunders Company, Philadelphia, pp. 296-299 (1989).							
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Fikes et al.

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THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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